

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

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**UNITED STATES OF AMERICA,**

**v.**

**(1) STRYKER BIOTECH, LLC,  
(2) MARK PHILIP,  
(3) WILLIAM HEPPNER,  
(4) DAVID ARD and  
(5) JEFFREY WHITAKER,**

**Defendants.**

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**Criminal No: 09-CR-10330-GAO**

**LEAVE TO FILE GRANTED ON  
NOVEMBER 3, 2011**

**REPLY BRIEF OF DEFENDANTS  
STRYKER BIOTECH, LLC AND MARK PHILLIP IN SUPPORT OF  
DEFENDANTS' MOTIONS TO SEVER THE FALSE STATEMENT COUNT**

Since the outset of this prosecution, the Government represented to Defendants and to the Court that the False Statement Count does not “relate to the conduct of” *any* of the four individual defendants. Yet, when confronted with Defendants’ motions to sever the False Statement Count pursuant to Rule 8(b), the Government changed course abruptly and obtained a Superseding Indictment from a new grand jury that, on the basis of no new evidence, alleges that the conduct underlying the False Statement Count was an “overt act” of the Conspiracy Count with which all of five of the defendants are charged. The law is clear, however, that the Government cannot evade Rule 8(b) through the expedient use of the grand jury process. As explained below, the Superseding Indictment’s newly concocted “overt act” allegation flies in the face of numerous factual representations that the Government previously made to Defendants and to the Court (including factual representations that the Government used to persuade Chief Magistrate Judge Dein to deny Defendants’ motion for a bill of particulars). In light of those prior factual representations, the inclusion of that new “overt act” allegation in the Superseding

Indictment is either the result of a cynical attempt on the part of the Government to evade Rule 8(b), or the result of a fundamental legal misunderstanding on the part of the Government as to what evidence it would need to adduce at trial to prove up that allegation. In either case, the new “overt act” allegation lacks an objectively “firm basis in fact” and is thus insufficient to avoid severance of the False Statement Count. Rather than risk having to declare a mistrial after empanelment of the jury, the Court should exercise its discretion to test prior to commencement of trial the factual and legal basis of the Government’s newfound theory of why joinder of the False Statement Count is proper under Rule 8(b).

### **INTRODUCTION**

In opposing Defendants’ motions to sever Count 15 of the Original Indictment (hereinafter the “False Statement Count”), the Government argued that the False Statement Count was properly joined under Rule 8(b) because it “charges an overt act done by a co-conspirator [defendant Stryker Biotech] in furtherance of” the separately charged conspiracy to “evade and frustrate efforts by the FDA to regulate the safety and efficacy of STRYKER BIOTECH medical devices . . . through the deliberate manipulation of physicians into using an unapproved and untested mixture of OP-1 and Calstrux” (hereinafter the “Conspiracy Count”). This supposed “link” between the False Statement Count and the Conspiracy Count was **(1)** not discernible from the face of the Original Indictment; **(2)** not supported by any of the evidence presented over the course of 18 months to the grand jury that returned the Original Indictment; **(3)** never revealed in discovery provided by the Government during the nearly two years after the Original Indictment was returned in October 2009; and **(4)** irreconcilable with several factual representations that the Government had earlier made to Defendants and to the Court during the course of this litigation.

In an effort to legitimize its newly concocted theory of joinder, the Government utilized a new grand jury to return the Superseding Indictment on October 11, 2011. In marked contrast to the Original Indictment, the Superseding Indictment explicitly alleges that “Stryker Biotech’s” April 2007 filing of a “false” annual regulatory report concerning OP-1 Putty (the alleged conduct from which the False Statement Count arises) was an “overt act” of the Conspiracy Count.<sup>1</sup> The addition of this overt act allegation was not based the Government’s presentation of any new evidence to the grand jury: At the October 31, 2011 arraignment on the Superseding Indictment, the Government stated that it had provided discovery in connection with the Superseding Indictment. That discovery confirmed that no additional evidence or witness testimony was presented to the grand jury that returned the revised Indictment. Indeed, the Superseding Indictment does not even *allege* the essential facts that the Government would need to prove at trial to establish that the filing of the 2007 Annual Report was an “overt act” of the conspiracy alleged in the Conspiracy Count. *See infra* at 8-10 (discussing the legal definition of “overt act”). Rather, the allegation is entirely conclusory.

But that is not all. The new overt act allegation is also utterly irreconcilable with factual representations made by the Government both before *and after* the return of the Superseding Indictment. In its response to a July 21, 2010 order entered by Chief Magistrate Judge Dein, the Government represented that the filing of the “false” 2007 Annual Report did not “relate to the conduct of” *any* of the individual Defendants in this case. Moreover, the Government never

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<sup>1</sup> The False Statement Count was previously Count 15 in the Original Indictment and is now Count 13 in the Superseding Indictment. The Conspiracy Count was previously Count 6 in the Original Indictment and is now Count 1 in the Superseding Indictment. Although the Superseding Indictment alters the “offense prong” of the charged conspiracy (substituting wire fraud for felony misbranding), the Superseding Indictment’s new overt act allegation clearly cannot be ascribed to *that* change. Just as with the Original Indictment, the Superseding Indictment describes the alleged conspiracy as one to “evade and frustrate efforts by the FDA to regulate the safety and efficacy of STRYKER BIOTECH medical devices . . . through the deliberate manipulation of physicians into using an unapproved and untested mixture of OP-1 and Calstrux.” Superseding Indictment, ¶ 57.

asserted at any time, either explicitly or implicitly, that some unindicted Stryker Biotech employee both (1) was a member of the alleged conspiracy to defraud surgeons, and (2) willfully made (or caused to be made) the false statement allegedly contained in the 2007 Annual Report in an effort to further that conspiracy.<sup>2</sup> Considered as a whole, the Government has thus effectively conceded that it would not be able to prove at trial all the legally essential elements of the Superseding Indictment's "overt act" allegation.

It appears that the Government's purpose in adding this new, factually unsupported "overt act" allegation to the Superseding Indictment was to defeat Defendants' motions to sever the False Statement Count. Indeed, less than ten minutes after the Superseding Indictment was docketed, Government counsel sent an e-mail to Defendants' counsel asserting that the Superseding Indictment rendered Defendants' severance motions "moot." Levy Decl., Ex. 4.

Contrary to the Government's assumption, the Court is not obligated to accept at face value the Superseding Indictment's conclusory allegation that the conduct underlying the False Statement Count was an "overt act" of the Conspiracy Count. *See, e.g., United States v. Velasquez*, 772 F.2d 1348, 1356 (7th Cir. 1985) (holding that, although the indictment alleged a link between separate cocaine and heroin counts, those counts were misjoined under Rule 8(b) because that alleged link was not supported by any evidence). The Court clearly has the discretion under Rule 8(b) to test, prior to trial, whether that allegation actually has "a firm basis in fact." *United States v. Arruda*, 715 F.2d 671, 678 (1st Cir. 1983); *see also United States v. Camacho*, No. 94-CR-00313, 1996 WL 137318, at \*2 (S.D.N.Y. Mar. 26, 1996) (requiring the government to submit evidence for *in camera* review, and to provide the defendants with an attorney affidavit, where the superseding indictment included a new allegation purporting to link

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<sup>2</sup> Neither the Original nor Superseding Indictment identifies the Stryker Biotech employee who willfully made (or caused to be made) the alleged false statement contained in the 2007 Annual Report. Instead, each of those charging instruments refers simply to the entity "Stryker Biotech."

two otherwise misjoined counts); *United States v. Nachamie*, 101 F. Supp. 2d 134, 153–54 (S.D.N.Y. 2000) (“In order to properly exercise its ‘virtually unreviewable’ discretion regarding whether joinder is proper, a court must have the power to inquire into the Government’s theory of joinder.”).<sup>3</sup> If the Court does not test the Government’s asserted basis for joinder prior to trial, and it then becomes clear *at trial* that the Government’s asserted basis for joinder was devoid of evidence all along, a mistrial will be the likely outcome. *Cf. Velasquez*, 772 F.2d at 1356.

## ARGUMENT

### **I. The Government’s Argument that the Conduct Underlying the False Statement Count Was an “Overt Act” of the Conspiracy Count is Irreconcilable with Numerous Factual Representations that the Government Made Subsequent to the Return of the Original Indictment.**

The False Statement Count alleges that, in April 2007, Stryker Biotech filed an annual regulatory report with the FDA stating that, because “two units [of OP-1 Putty] are used” per patient, an estimated 3,117 patients had been treated with OP-1 Putty between April 2006 and March 2007. The False Statement Count charges that, by making that statement, “Stryker Biotech” violated 18 U.S.C. § 1001 because the company supposedly possessed information suggesting that approximately 4,795 patients had been treated with the device during that time period. Neither the Original Indictment nor the Superseding Indictment identifies the individual Stryker Biotech employee who willfully made, or caused to be made, the allegedly “false statement” in the 2007 Annual Report.

Contrary to the argument the Government advanced in its brief in opposition to Defendants’ severance motions, the Original Indictment did not even *allude* to the possibility that the allegedly false statement at issue was an “overt act” of, and therefore part of the “same

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<sup>3</sup> Defendants Stryker Biotech and Mark Philip respectfully request that the Court construe Defendants’ previously-filed severance motions as seeking severance of Count 13 of the Superseding Indictment in order to avoid the necessity of re-briefing the arguments stated therein in a new motion and delaying the ripeness of the matter for decision.

series” of acts as, the conspiracy alleged in the Conspiracy Count.<sup>4</sup> Indeed, the Government itself acknowledged, on numerous occasions, that other than the fact that the False Statement Count and the Conspiracy Count share a common corporate defendant — a commonality that is indisputably insufficient for joinder under Rule 8(b), *see, e.g. United States v. Lech*, 161 F.R.D. 255, 256 (S.D.N.Y. 1995) (Sotomayor, J.) — those counts share no other links.<sup>5</sup> By way of example, the Government made the following representations during the course of this case:

- In successfully opposing Defendants’ request for certain *Brady* material, the Government suggested that the False Statement Count did “not appear to be relevant” to the Conspiracy Count. *See* Govt. Opp. Br., Dkt. #45, at 3 n.3 (Apr. 8, 2010).
- In opposing Defendants’ motion for a bill of particulars, the Government told Chief Magistrate Judge Dein that “[t]here’s a scheme, a fraud scheme alleged in the indictment, a conspiracy, a misbranding, a series of misbranding charges that all arise from the illegal promotion together of . . . OP-1 and Calstrux . . . . The essence of the [alleged] scheme’s well known. . . . There [are] no extra particularizations that we can give [them] . . . .” Levy Decl., Ex. 1 (oral argument transcript). The Government did not in any way suggest that the Conspiracy Count also involved the alleged falsification of the 2007 Annual Report. Rather, the Government repeatedly assured Chief Magistrate Judge Dein that the Original Indictment, the grand jury transcripts, and the grand jury exhibits gave Defendants a clear “roadmap” of the case they had to defend. *See* Govt. Opp. Br., Dkt. #59, at 4 (June 14, 2010). On the basis of those assurances, Chief Magistrate Judge Dein chose to deny Defendants’ motion. *See generally* Order, Dkt. #67 (July 21, 2010).

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<sup>4</sup> In telling contrast, the Original Indictment made explicit that the Conspiracy Count *was* linked to the five wire fraud counts and the eight felony misbranding counts: the Original Indictment very clearly identified as “overt acts” or “manner and means” each of the thirteen specific e-mail transmissions underlying those wire fraud and felony misbranding counts. *See* Original Indictment, ¶¶ 62-63. The False Statement charge was not alleged as an overt act in the Original Indictment.

<sup>5</sup> The Government now hypothesizes that, had the 2007 Annual Report disclosed that 4,795 patients (rather than 3,117 patients) had been treated with OP-1 Putty during the April 2006-March 2007 time period, this disclosure alone would have caused the FDA to suspect the presence of off-label *use* of OP-1 Putty, which in turn would have caused the agency to suspect the presence of off-label mixing of Calstrux with OP-1, which in turn would have caused the agency to suspect not merely that the Stryker Biotech sales force was *promoting* that mixture but *defrauding* surgeons into using that mixture. This highly inferential chain of logic is rendered implausible in light of the fact that, as documented by the FDA itself, Stryker Biotech’s regulatory department *voluntarily disclosed* to the FDA in August 2006 that 90% of the Calstrux units sold by the company were being used by surgeons to extend OP-1. *See* Levy Decl., Ex. 5 (internal FDA document that the Government produced to Defendants as part of automatic discovery).

- On July 21, 2010, Chief Magistrate Judge Dein ordered the Government to “clarify whether any of the paragraphs [of the Original Indictment] which refer only to ‘Stryker Biotech’ relate to conduct of the individual defendants [Philip, Heppner, Ard, and Whitaker].” *See* Order, Dkt. #67, at 2 (July 21, 2010). The False Statement Count was (and still is) composed entirely of paragraphs referring to “Stryker Biotech,” without any mention of either the individual defendants or any other specific Stryker Biotech employee. In the letter it provided to Defendants in response to Chief Magistrate Judge Dein’s order, the Government identified the several paragraphs of the Original Indictment in which references to “Stryker Biotech” did, in fact, “relate to the conduct of” at least one of the individual defendants; none of the False Statement Count paragraphs were identified. Levy Decl., Ex. 2 (Government’s letter).
- During oral argument on the Defendants’ motion to dismiss the portion of the Conspiracy Count charging them with conspiring to defraud the FDA of its lawful regulatory functions, the Government sought to identify for the Court “a number of charges in the [Original Indictment] that talk about [the conspiratorial] conduct that specifically . . . implicates the FDA.” The Government pointed to (1) Defendants’ “preventing a ‘dear doctor’ letter from going out in or about March of 2006;” (2) Defendants’ “misrepresent[ing] to surgeons the nature of the FDA’s approval [because] that specifically steps on the toes of the FDA;” and (3) Defendants’ creation of unapproved “labeling for OP-1.” Levy Decl., Ex. 3 (argument transcript). The Government did not mention Stryker Biotech’s filing of the allegedly “false” 2007 Annual Report as a conspiratorial act done in furtherance of the separately charged conspiracy to defraud the FDA. *See id.*

It was only when confronted with Defendants’ severance motions that the Government conveniently reversed course and decided to argue that the False Statement Count “charges an overt act done by a co-conspirator [defendant Stryker Biotech] in furtherance” of the Conspiracy Count. Govt. Opp. Br., Dkt. # 144, at 5 (Sept. 30, 2011).

## **II. Securing the Superseding Indictment Does Not Legitimize the Government’s Implausible Joinder Theory.**

Eleven days after filing its opposition brief to Defendants’ severance motions, the Government used a new grand jury to return the Superseding Indictment, which, in marked contrast to the Original Indictment and contrary to the prior governmental representations detailed above, explicitly alleges that the conduct underlying the False Statement Count was an “overt act” of the Conspiracy Count. At the October 31, 2011 arraignment hearing before Chief Magistrate Judge Dein, the Government stated that it had provided Defendants with discovery in

connection with the Superseding Indictment. Those few additional discovery materials do not contain *any* evidence or testimony that had not been previously presented to the original grand jury.

Defendants agree with the Government that “[a] conspiracy count *can* be a sufficient connecting link between co-defendants and separate substantive offenses to permit their joinder in a single indictment.” *United States v. Luna*, 585 F.2d 1, 4 (1st Cir. 1978) (emphasis added). Yet, the First Circuit has made clear that, in order to satisfy Rule 8(b), it is not enough for an indictment to *allege* a “sufficient connecting link” between a conspiracy count and another separately charged substantive offense. *United States v. Arruda*, 715 F.2d 671, 678 (1st Cir. 1983). Rather, the linking allegation “must have a firm basis in fact,” *id.*, such that the Government has an objectively “reasonable expectation of proving the required connection,” *United States v. Green*, 324 F. Supp. 2d 311, 319 (D. Mass. 2004) (internal quotations omitted); *see also Luna*, 585 F.2d at 4 (holding that a conspiracy count “will not rectify otherwise improper joinder” unless “the count has been added in good faith, and a factual basis for it exists”).<sup>6</sup>

In this case, the Government’s representations to Defendants and to the Court demonstrate the lack of any “firm basis in fact” for the Superseding Indictment’s allegation that the conduct underlying the False Statement Count was an “overt act” of the Conspiracy Count. As an initial matter, the Government has made numerous prior factual representations that fundamentally conflict with the Superseding Indictment’s new “overt act” allegation.

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<sup>6</sup> The case law sometimes uses the term “bad faith” to describe a situation where the alleged link between two otherwise misjoined counts does not have a “firm basis in fact.” *See, e.g., United States v. Turkette*, 656 F.2d 5, 8 (1st Cir. 1981). This is somewhat of a misnomer. Under First Circuit law, the issue is not whether the Government acted in *subjective bad faith* in issuing the superseding indictment (*e.g.*, acted out of vindictiveness or some similarly inappropriate motive), but rather whether, viewed objectively, a firm factual basis exists for the allegation that supposedly “links” the indictment’s counts. *See Velasquez*, 772 F.2d at 1354-55 (discussing First Circuit law).



Moreover, because the Superseding Indictment (like the Original Indictment) fails to identify which individual within Stryker Biotech engaged in the willful submission of the allegedly “false” 2007 Annual Report, the Government has no basis to assert that it could *prove* that this unidentified (and apparently unknown) employee had both (1) agreed to join the alleged conspiracy to defraud surgeons into mixing OP-1 with Calstrux and (2) then willfully falsified the 2007 Annual Report in an effort to further that conspiracy. *See* Pattern Criminal Jury Instructions for the District Courts of the First Circuit at § 4.18.371(1) (defining “overt act” as an act taken by a co-conspirator “in an effort to further the purpose of the conspiracy”).

The Government’s argument that defendant “Stryker Biotech” is the common “co-conspirator” between the False Statement Count and the Conspiracy Count is insufficient to satisfy Rule 8(b). While Stryker Biotech can be convicted of conspiracy if two or more of its employees conspire with one another, Stryker Biotech itself cannot “form the mental state required to conspire with another.” *United States v. Sain*, 141 F.3d 463, 475 (3d Cir. 1998); *see also United States v. Peters*, 732 F.2d 1004, 1008 (1st Cir. 1984) (recognizing that, under *respondeat superior* principles, a company can be convicted of conspiracy if two or more of its agents conspire with one another). Thus, the fact that “Stryker Biotech” is charged in both the False Statement Count and the Conspiracy Count reflects merely the realities of the *respondeat superior* doctrine; it says nothing about whether someone at Stryker Biotech willfully falsified the 2007 Annual Report in an effort to further the objectives of the separately charged conspiracy to defraud surgeons.<sup>7</sup>

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<sup>7</sup> This point also applies *a fortiori* to the Superseding Indictment’s allegation in the “manner and means” section of the Conspiracy Count that the 2007 Annual Report was willfully falsified in an effort “to conceal the ongoing conspiracy” to defraud surgeons into mixing Calstrux with OP-1. Superseding Indictment, ¶ 58(j).

It might be that the Superseding Indictment’s new “overt act” allegation is based on the Government’s theory that any act legally attributable to “Stryker Biotech” constitutes an “overt act” of the alleged conspiracy so long as it might have had the incidental *effect* of allowing that conspiracy to continue — even if the individual Stryker Biotech employee who committed that act was not a member of that conspiracy to defraud surgeons, had no intent to further that conspiracy, and may not even have known about the existence of that conspiracy. But such a theory presumes a definition of “overt act” that is clearly wrong as a matter of law. *See United States v. Upton*, 559 F.3d 3, 11 (1st Cir. 2009) (holding that actions of concealment are not part of a conspiracy unless they are taken “done in furtherance” of the “central objective of the conspiracy”); Pattern Criminal Jury Instructions for the District Courts of the First Circuit at § 4.18.371(1) (“A person who has no knowledge of a conspiracy, but simply happens to act in a way that furthers some object or purpose of the conspiracy, does not thereby become a conspirator.”). And the First Circuit has made clear that Rule 8(b) is not satisfied by the assertion of a “link” that is legally erroneous. *See United States v. Turkette*, 632 F.2d 896, 907 (1st Cir. 1980) (holding that where a conspiracy allegation is “based on a legal interpretation that is improper, the court cannot base its 8(b) ruling on the written words [of the indictment] alone but must determine if, under [a] correct legal theory, joint action was actually involved”), *reversed on other grounds* at 452 U.S. 576 (1981).

Alternatively, the Superseding Indictment could be viewed as a cynical attempt on the Government’s part to evade both Rule 8(b) and Rule 14: On the *exact same* body of evidence that it had presented to the original grand jury, the Government secured a new grand jury’s approval of an “overt act” allegation that (1) the original grand jury had not approved and (2) prior to being confronted with Defendants’ severance motions, the Government had actually *disclaimed* through myriad factual representations to Defendants and to the Court. The

circumstances here indeed suggest that the Government's motivation in adding the 2007 Annual report allegation as an "overt act" in the Superseding Indictment was simply to save the joinder of the False Statement Count so as to enable the Government to introduce against all of the defendants prejudicial extrinsic evidence of an alleged lie told to the FDA by some unidentified Stryker Biotech employee.

Regardless, there is no basis for concluding that the Government has an objectively "reasonable expectation that sufficient proof will be forthcoming at trial" to prove up the Superseding Indictment's new overt act allegation. *United States v. Castellano*, 610 F. Supp. 1359, 1397 (S.D.N.Y. 1985) (internal quotations omitted); *see also Green*, 324 F. Supp. 2d at 319 (holding that joinder is improper under Rule 8(b) if government lacks reasonable expectation of actually proving at trial the alleged connection between various counts). Under these irregular circumstances, this Court should, prior to trial, evaluate the legal and factual basis of the Government's theory of joinder. *See Nachamie*, 101 F. Supp. 2d at 153–54 (holding that "a court must have the power to inquire into the Government's theory of joinder" prior to trial); *United States v. Camacho*, No. S12 94 CR. 313, 1996 WL 137318, \*2, (S.D.N.Y. March 26, 1996) (requiring the Government to make a pre-trial evidentiary submission so that the court could determine whether the superseding indictment's newly-alleged link between multiple RICO charges had a true factual basis, or whether the allegation had been "tacked on . . . for strategic or tactical reasons of the government's own devising"). As the Court recognized in *Castellano*, in assessing whether joinder is proper under Rule 8(b), a district court is entitled to engage in "pretrial scrutiny" of the "evidence [the Government] represents it expects to be able to introduce at a joint trial." 610 F. Supp. at 1397.

To be clear, Defendants are not asking the Court to engage a full-blown "sufficiency of the evidence" review of the Superseding Indictment. Rather, Defendants are merely asking the

Court to require the Government to detail for the Court what evidence it possesses to prove up the Superseding Indictment's new "overt act" allegation. *See Camacho*, 939 F. Supp. 203, 204–06 (S.D.N.Y. 1996). Such a step is especially warranted where, as here, the Government has produced to Defendants the documents and testimony presented to the grand jury in support of the new "overt act" allegation. If the Government can satisfy such a pre-trial inquiry, then Rule 8(b) will be satisfied, and the question for the Court will then be whether severance is nevertheless appropriate as a discretionary matter under Rule 14.<sup>8</sup> If, however, the Government cannot survive this pre-trial assessment, then severance of the False Statement Count under Rule 8(b) will be mandatory.

Pre-trial testing of the legal and factual basis of Government's joinder theory is not only fair, it is also prudent. If the Court does not engage in such pre-trial testing and it then becomes evident during trial that the Superseding Indictment's new "overt act" allegation lacks a factual and/or legal basis, it may be necessary for the Court to declare a mistrial. *See Schaffer v. United*

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<sup>8</sup> Even if the Court were to assume that Rule 8(b) has been satisfied, the Government has offered no persuasive argument for why the False Statement Count should not be severed as a matter of discretion under Rule 14. If the Government were permitted to argue at trial that "Stryker Biotech" lied to the FDA in the 2007 Annual Report, this would, at a bare minimum, run a high risk of compromising the jury's ability to fairly and impartially assess the veracity of the Government's separate allegation that the individual defendants engaged in a scheme to defraud surgeons about the safety and efficacy of OP-1 and Calstrux — the jury might conclude that, if the individual defendants' employer is "a liar," they must be liars too. Moreover, the Government is now seeking to use the joinder of the False Statement Count as a gateway to the introduction of other inflammatory, extrinsic allegations involving Defendant Mark Philip. *See Superseding Indictment* ¶ 59(h) (alleging that one of the "manner and means" of the Conspiracy Count was Philip's October 2007 attempt to delete an internal company document suggesting that fewer than two units of OP-1 Putty were being used per patient), ¶ 59(i) (alleging that one of the "manner and means" of the Conspiracy Count was Philip's February 2008 attempt to have a fellow employee to lie on an internal company call regarding the number of units of OP-1 Putty that were being used per patient). Those allegations previously had served as the foundation of Count 16 of the Original Indictment, a separate false statement charge brought solely against Philip that the Government *never* asserted was part of the "same series of acts" as the Conspiracy Count and that the Government ultimately *voluntarily dismissed*. The Government's decision to "resurrect" those allegations in the Superseding Indictment reveals the paramount importance the Government places on prejudicial spillover. Furthermore, while it would be unfair to make *any* of the individual defendants suddenly have to defend themselves against the alleged "falsification" of the 2007 Annual Report, it would be particularly unfair to Philip because, as the Government knows, the Government spent a year in the grand jury attempting to tie Philip to that alleged conduct but was unable to do so.

*States*, 362 U.S. 511, 515–16 (1960) (“[T]he trial judge has a continuing duty at all stages of the trial to grant a severance if prejudice does appear. And where, as here, the charge which originally justified joinder turns out to lack the support of sufficient evidence, a trial judge should be particularly sensitive to the possibility of such prejudice.”); *cf. Velasquez*, 772 F.2d at 1356 (finding prejudicial misjoinder under Rule 8(b), and vacating convictions, where the trial evidence ultimately failed to support the government’s asserted basis for joinder). It will be too late during trial to unring the bell, the jury already having heard about the highly inflammatory accusation of “lying” to the FDA. The Court can avoid the extreme consequence of a mistrial by testing the Government’s joinder theory now in ruling on Defendants’ severance motion.<sup>9</sup>

### **CONCLUSION**

For the foregoing reasons, Defendants respectfully request that this Court sever Count 13 from the remainder of the Superseding Indictment, and order separate trials.

Respectfully submitted,

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<sup>9</sup> Severing the False Statement Count is required under Rule 8(b) and Rule 14, but severance alone will not protect Defendants’ right to a fair trial. The Court should also exclude, under Rule 404(b), evidence of conduct that, though included within the “manner and means” and/or “overt acts” sections of the Conspiracy Count, in fact bears no relationship to the alleged conspiracy to defraud surgeons into mixing Calstrux with OP-1. Accordingly, presuming the Government cannot make a showing that there is a factual basis for its revisionary view of the False Statement Count, the Defendants request that the Court (1) exclude evidence pertaining to this conduct as alleged in Paragraphs 58(j), 58(k), 59(f), 59(h), and 59(i), and (2) strike those paragraphs from the Superseding Indictment as surplusage.

**CERTIFICATE OF SERVICE**

I hereby certify that this document, filed through the ECF system, will be served electronically to the registered participants identified on the Notice of Electronic Filing (“NEF”), and that paper copies will be sent via electronic mail to those identified on the NEF as non-registered participants on November 2, 2011.

/s/ Joshua S. Levy  
Joshua S. Levy